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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,573	03/22/2001	Hector F. DeLuca	1256-00721	9707

7590

01/20/2006

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/815,573		DELUCA ET AL.	
	Examiner		Art Unit	
	Abigail M. Cotton		1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 5, 2005, has been entered.

Claims 8-14 are pending in the instant application and are being examined on the merits herein.

Applicant's arguments filed December 5, 2005 with respect to the rejection(s) of claim(s) 8-14 under 35 U.S.C. 103(a) have been fully considered and are persuasive because WO 96/24258 does not specifically teach a method with dairy cows. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of WO 96/24258 in view of U.S Patent No. 5,145,695 to Smith et al, issued September 8, 1992.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca et al. (WO 96/24258) in view of U.S. Patent No. 5,145,695 to Smith et al, issued September 8, 1992.

Deluca et al. discloses a method of improving utilization of phosphorous such as to reduce or perhaps eliminate dietary requirement of phosphorous in animals (see abstract, page 3, lines 13-15, in particular) including in commercially significant mammals such as cattle (see page 10, lines 5-20, in particular.) Deluca et al. teaches the method involves feeding animals with the instantly claimed 1 α -hydroxylated vitamin D compounds (see pages 7-8, in particular) in the effective amounts, about 5-40 μ g/kg, which is within the instantly claimed range (see page 10, lines 20-22 and claim 12, in particular.) Deluca et al. also teaches that the composition may be in the form of a top dressing (see page 9, line 3, in particular.) See also abstract, page 5 line 30 to page 6, line 3, page 9 lines 15-17 and claims 18-20, in particular.

DeLuca et al. does not expressly disclose the method herein comprising replacing all inorganic phosphorus in a diet with the known effective amount of a 1 α -hydroxylated vitamin D of prior art. DeLuca et al. also do not expressly disclose that said feed contains 0% by weight of an inorganic phosphorous supplement.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to replace all inorganic phosphorus in a diet with the known effective amount of 1 α -hydroxylated vitamin D of the prior art, and to provide said feed containing 0% by weight of an inorganic phosphorous supplement.

One having ordinary skill in the art at the time the invention was made would have been motivated to replace all inorganic phosphorous in a diet with the known effective amount of 1 α -hydroxylated vitamin D of the prior art, and to provide said feed containing 0% by weight of an inorganic phosphorous supplement, since the known method of improving utilization of phosphorous that is capable of reducing or minimizing or perhaps eliminating dietary requirements of phosphorous in animals such as cattle, and comprising feeding with the same effective amount of the 1 α -hydroxylated vitamin D, about 5-40 $\mu\text{g/kg}$, has been disclosed by DeLuca et al.

Thus, DeLuca et al. is seen to clearly provide the motivation for the instant method of eliminating the dietary requirement of phosphorous or replacing all inorganic

phosphorous in a diet, by administering the same effective amount of the same vitamin D compound to cattle.

DeLuca et al. have furthermore provided the motivation for elimination or replacing all inorganic phosphorous in a diet for the sake of eliminating or reducing pollution by the phosphorous, by teaching that "low phosphorus containing animal feeds reduce the pollution effects on the environment since less phosphorous is excreted in the animal's feces which are then spread on agricultural land."

DeLuca et al. does not specifically teach performing the method with cattle that are dairy cows, as recited in the claims.

However, Smith et al. teaches that dairy cows are commercially significant, particularly for the production of milk in the dairy industry (see column 1, lines 5-40, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to perform the method of DeLuca et al. on the specific type of cattle, dairy cows, of Smith et al, because DeLuca et al. teaches that the method is suitable for commercially significant mammals including cattle, and Smith et al. teaches that dairy cows are commercially significant cattle. Thus, one of ordinary skill in the art would have been motivated to perform the method of DeLuca et al. on the dairy cows of Smith et al. with the expectation of achieving the reduced pollution and low phosphorous benefits.

Thus, the claimed invention as a whole is clearly prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments with respect to claims 8-14 have been considered but are moot in view of the new ground(s) of rejection.

In particular, Applicant's note that the DeLuca et al. reference does not specifically teach dairy cows. However, as discussed in the rejection above, this deficiency of DeLuca et al. is remedied by Smith et al's teaching of dairy cows as cattle that is commercially significant.

Applicants furthermore argue that it would not be obvious to apply a low phosphorous feed method to lactating cows, because lactating cows require a sufficient amount of phosphorous in their diets to maintain milk yields. However, DeLuca et al. clearly teaches that the prior art Vitamin D compounds increase the biological utilization of phosphorous from the non-inorganic source phytate, and thus can allow for a lower amount of phosphorous supplements (a low phosphorous diet) and can perhaps even allow for the elimination of inorganic phosphorous supplements in the diet (see page 3, lines 1-15, in particular.) Accordingly, one of ordinary skill in the art would reasonably expect to achieve this improved utilization of phosphorus in mammals such as cattle as

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taught by DeLuca et al., and including in lactating cattle, and thus would reasonably expect that a reduced phosphorous supplement diet could be provided in such lactating cattle due to the improved phosphorous utilization brought about by administration of the vitamin D compounds.

Applicants further argue via supporting documents ("Tables of Nutrient Requirements" and "Nutrient Requirements of Dairy Cattle") that a phosphorous deficiency, especially in dairy cows, can have serious health consequences. The Examiner agrees that these documents indicate that phosphorus is a necessary part of a dairy cow diet. However, De Luca et al. also teaches that phosphorous is obtained in animal diets through ingestion of plant food such as phytate (see page 1, lines 5-30, in particular), and teaches that the utilization of such phytate can be improved with the vitamin D compounds, such that extra inorganic phosphate supplements can be reduced and even eliminated from the diet (see page 3, lines 1-30, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would understand that the necessary dietary phosphorous, as indicated by the documents cited by Applicants, could still be achieved via ingestion of phytate or other plant-based feeds in the method of DeLuca et al, with the utilization of such phytate being enhanced by the vitamin D compounds such that little or even no phosphorous supplement is required.

Applicants furthermore argue that DeLuca et al's teaching that the animal feed can "perhaps" eliminate the need for supplemental phosphorus (see abstract, in particular) is not an affirmative teaching to eliminate or replace all inorganic phosphorous in the diet. The examiner recognizes that obviousness can only be established by modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, DeLuca et al. teaches that the vitamin D compound enhances the utilization of sources of phosphorus such as phytate found in food-stuffs such that the amount of supplemental phosphorus required is at least reduced, and may even be eliminated, and that such phosphorous reduction and/or elimination reduces pollution. Accordingly, DeLuca et al. clearly provides motivation to provide the instant vitamin D compound with a low phosphorous diet, and even without any inorganic phosphorous supplements, with the expectation of the likelihood of achieving sufficient phosphorous intake from non-supplemental sources such as phytate, and with the expectation of reducing phosphorous pollution.

Applicants also refer to the examples as shown in Tables 2-4 of the instant Specification to show the results for low and high phosphorous diets with and without the addition of the vitamin D compounds. In particular, Applicant's note that both high (treatment 2) and low phosphorous diets (treatment 4) with the addition of vitamin D

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compounds gives adequate milk yields, of 36.9 and 37.6 kilograms per day, respectively as exemplified in Tale 2 of the instant Specification. The Examiner agrees the these specific examples illustrate that both high and low phosphorous diets with the vitamin D compound yield similar milk production quantities. However, these results are not unexpected over the teachings of DeLuca et al. as previous discussed, which teaches that the vitamin D compounds can enhance utilization of phosphorus to allow for lower phosphorous supplementation. The Examiner further notes that, interestingly, Applicants examples appear to show that a similar "adequate" milk production value (37.3 kg/day) is achieved even for the low phosphorous diet in which the vitamin D compound is not provided (treatment 3), suggesting that the amount of phosphorous received by the "low phosphorous" diet as administered by Applicants is capable of providing sufficient phosphorous for desired milk production, even without the vitamin D compound. Thus, Applicant's data do not appear to show any unexpected results in milk production that are achieved by the administration of the vitamin D compound and that are not already taught and/or rendered obvious by the teachings of Deluca et al. and Smith et al.

Conclusion

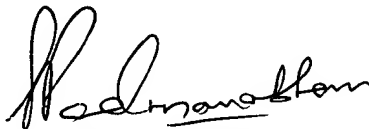
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC


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